REMARKS/ARGUMENT

Description of Amendments

Applicant has added claim 26 and cancelled claims 17 and 18. As amended, claims 1, 2, 4, 6, 9-16, and 26 are now pending and under examination, and claims 3, 5, 7, 8, and 19-25 are withdrawn.

Information Disclosure Statement of Sep. 1, 2004

The Examiner refused to consider an Information Disclosure Statement (IDS) allegedly filed on Sep. 1, 2004 on the ground that the IDS does not include a 1449 form. Applicant's file does not indicate that an IDS was filed on Sep. 1, 2004. The Examiner indicated in the Advisory Action that the IDS could be found in PAIR. However, this application is not available in public PAIR and is not available to Applicant in private PAIR. May Applicant request the Examiner to please send a copy of the alleged IDS to Applicant so that Applicant can properly address this issue?

Rejections under 35 U.S.C. §102

Claim 17 was rejected under 35 U.S.C. §102(e) as being anticipated by *Ding* (U.S. Patent Publication 2006/0089705). The cancellation of claim 17 renders this rejection moot.

Claims 1, 2, 6, and 10-18 were rejected under 35 U.S.C. §102 as being anticipated by *Vallana* (U.S. Patent Publication 2003/0078647). The cancellation of claims 17 and 18 renders their rejection moot. For the following reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1, 2, 6, and 10-16.

Independent claim 1 recites that "a prefabricated patterned tubular sleeve portion having independent drug-loaded elements, the tubular sleeve being releasably attached to an outer surface of a stent structure in an unexpanded condition, at least a portion of the patterned tubular sleeve portion being decoupled from the outer surface of the stent when the stent is in an expanded condition..." (emphasis added).

Vallana does not disclose anything that is "attached to an outer surface of a stent structure in an unexpanded condition [and] decoupled from the outer surface of the stent when the stent is in an expanded condition...." In *Vallana*, the nature of the physical contact

between the stent (2), and the sheath (5) or the fibers (4), does not change when the stent (2) is in an unexpanded or expanded condition. Therefore, it cannot be said that the sheath (5) or the fibers (4) is attached to the stent (2) when the stent (2) is unexpanded, and uncoupled from the stent (2) when the stent (2) is expanded. Accordingly, *Vallana* does not anticipate independent claim 1. Dependent claims 2, 6, and 9-16 are also not anticipated because they depend from claim 1.

Claims 1, 2, and 9-18 were rejected under 35 U.S.C. §102 as being anticipated by *Tartaglia* (U.S. Patent 5,700,286). The cancellation of claims 17 and 18 renders their rejection moot. For the following reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1, 2, and 9-16.

One disadvantage of a prior art drug eluting stent is that when the stent is expanded, the drug-coated stent surfaces are stretched, causing uneven distribution of coated drug on stent surfaces. One object for the present invention is overcome this disadvantage of the prior art.

The claimed invention includes independent drug-loaded elements, which are not stretched when the stent structure expands from the unexpanded condition to the expanded condition. Consequently, the expansion of the stent structure does not cause an uneven distribution of coated drug.

Tartaglia discloses an expandable stent structural member (22) and **a** planar sheet or film (24) of polymeric material that is wrapped around the stent (column 4, lines 19-49). The Examiner contended that the planar sheet or film (24) is the independent drug-loaded elements of the claimed invention. Applicant respectfully disagrees.

Tartaglia does not disclose **independent** drug-loaded element**s**. Instead, it discloses only a single planar sheet or film (24). The single planar sheet or film (24) cannot be **independent** drug-loaded element**s**.

In the Office Action of November 7, 2006, the Examiner contended:

> "the slits 30 produce independent elements even through they are attached at a first end. Applicant's claim language does not exclude this configuration. The free ends are allowed to move independent from the others and are therefore considered independent. *Tartaglia* states, 'the film of polymeric material also has a free end 28, and can have one or more slits 30 in the polymeric film transverse to the axis 32 of the

> stent to accommodate possible uneven expansion of the underlying stent structural member (4:37 et seq.)."

Apparently, the Examiner believed that the so-called "independent elements," allegedly produced by the slits (30), have free ends and are therefore independent.

Applicant respectfully disagrees with the Examiner's reading of *Tartaglia*. Contrary to the Examiner's contention, the slits (30) of *Tartaglia* do not produce "independent elements" that have free ends. As cited by the Examiner, *Tartaglia* discloses that the film (24) has only one free end (28); *Tartaglia* does not disclose a plurality of free ends. As shown in Figures 3 and 4, the slits (30) do not reach the free end (28) of the film (24) to produce a plurality of free ends. Therefore, both ends of the alleged "independent elements" are attached to one another.

Additionally, elements that are attached only at one end are not independent. The dictionary definition of "independent" is "not influenced." Elements that are attached at one end are not independent, because they are influenced by one another because of the attachment.

Furthermore, the independent drug-loaded elements of the claimed invention are not stretched when the stent structure expands from the unexpanded condition to the expanded condition. In *Tartaglia*, the planar sheet or film (24), which is wrapped around the stent structural member (22), will inevitably be subject to a stretching force when the stent structural member (22) expands, and this stretching force will stretch the planar sheet or film (24) to some extent, potentially causing uneven distribution of coated drug.

In view of the above remarks, Applicant respectfully submits that *Tartaglia* does not teach the limitation of independent drug-loaded elements and the limitation that the sleeve is not stretched when the stent structure expands from the unexpanded condition to the expanded condition. Accordingly, *Tartaglia* does not anticipate independent claim 1. Dependent claims 2 and 9-16 are also not anticipated because they depend from claim 1.

Rejection under 35 U.S.C. §103(a)

Claims 1, 2, 4, and 9-18 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Williams* (U.S. Patent 5,707,385) in view of *Tartaglia*. The cancellation of claims 17

and 18 renders their rejection moot. For the following reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection.

Williams discloses an expandable stent (16) stent and **an** expandable membrane (5) that is mounted on the expandable stent (see Abstract). When the stent (16) is expanded, the expandable membrane (5) is stretched (see claim 1 and column 2, lines 30-41). The Examiner conceded that *Williams* does not discloses a sleeve that includes independent drug-loaded elements, but contended that *Tartaglia* teaches independent elements separated by slits (30).

Applicant respectfully disagrees with the Examiner's reading of *Williams* and *Tartaglia*. First, as discussed above, *Tartaglia* does not teach independent elements separated by slits (30).

Second, neither *Williams* nor *Tartaglia* teaches the limitation that the sleeve is not stretched when the stent structure expands from the unexpanded condition to the expanded condition. As explicitly taught by *Williams*, its expandable membrane (5) is designed to stretch when the stent (16) expands from the unexpanded condition to the expanded condition (see claim 1 and column 2, lines 30-41). In *Tartaglia*, the planar sheet or film (24), which is wrapped around the stent structural member (22), will inevitably be subject to a stretching force when the stent structural member (22) expands, and this stretching force will stretch the planar sheet or film (24) to some extent, potentially causing uneven distribution of coated drug.

In view of the above remarks, the cited art does not teach each and every limitation of independent claim 1. Accordingly, independent claim 1 is patentable over the cited art. Dependent claims 2, 4, and 9-16 are also patentable because they depend from patentable claim 1.

Patentability of New Claim 26

New claim 26 is patentable because it depends from patentable claim 1. In addition, claim 26 recites the limitation that "each of the independent drug-loaded elements is releasably adhered to the outer surface of the stent structure in the unexpanded condition." This limitation is not taught or suggested by the cited art.

In light of the foregoing remarks, this application is considered to be in condition for allowance, and early passage of this case to issue is respectfully requested. If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 07-1850.

Respectfully submitted,

Date: March 7, 2007

/Song Zhu, Reg. No. 44,420/

Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza
Suite 300
San Francisco, CA 94111
Facsimile (415) 393-9887
Telephone (415) 954-0241
szhu@ssd.com

Song Zhu, Ph.D.
Attorney for Applicant
Reg. No. 44,420